4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0110]

Agency Information Collection Activities: Proposed Collection; Comment Request; Prescription

Drug Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements, including third party disclosure, contained in FDA's current regulations on prescription drug advertisements.

DATES: Submit either electronic or written comments on the collection of information by

[INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER.]

ADDRESSES: Submit electronic comments on the collection of information to

http://www.regulations.gov. Submit written comments on the collection of information to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane., rm. 1061, Rockville, MD 20852. All comments should be identified with the docket

number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Prescription Drug Advertisements--(OMB Control Number 0910-0686)--Extension Section 502(n) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352(n)) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. For prescription drugs and biologics, section 502(n) of the FD&C Act requires advertisements to contain "* * * a true statement * * * " of certain information including "* * * information in brief summary relating to side effects, contraindications, and effectiveness * * * " as required by regulations issued by FDA. FDA's prescription drug advertising regulations at § 202.1 (21 CFR 202.1) describe requirements and standards for print and broadcast advertisements. Section 202.1 applies to advertisements published in journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems. Print advertisements must include a brief summary of each of the risk concepts from the product's approved package labeling (§ 202.1(e)(1)). Advertisements that are broadcast through media such as television, radio, or telephone communications systems must disclose the major risks from the product's package labeling in either the audio or audio and visual parts of the presentation (§ 202.1(e)(1)); this disclosure is known as the "major statement." If a broadcast advertisement omits the major statement, or if the major statement minimizes the risks associated with the use of the drug, the advertisement could render the drug misbranded in violation of section 502(n) of the FD&C Act, section 201(n) of the FD&C Act (21 U.S.C. 321(n)), and FDA's implementing regulations at § 202.1(e).

Advertisements subject to the requirements at § 202.1 are subject to the PRA because these advertisements disclose information to the public. In addition, § 202.1(e)(6) and (j) include provisions that are subject to OMB approval under the PRA.

Reporting to FDA

Section 202.1(e)(6) permits a person who would be adversely affected by the enforcement of a provision of § 202.1(e)(6) to request a waiver from FDA for that provision. The waiver request must set forth clearly and concisely the petitioner's interest in the advertisement, the specific provision of § 202.1(e)(6) from which a waiver is sought, a complete copy of the advertisement, and a showing that the advertisement is not false, lacking in fair balance or otherwise misleading, or otherwise violative of section 502(n) of the FD&C Act.

Section 202.1(j), which sets forth requirements for the dissemination of advertisements subject to the standards in § 202.1(e), contains the following information collection that is subject to the PRA:

Under § 202.1(j)(1), a sponsor must submit advertisements to FDA for prior approval before dissemination if: (1) The sponsor or FDA has received information that has not been widely publicized in medical literature that the use of the drug may cause fatalities or serious damage; (2) FDA has notified the sponsor that the information must be part of the advertisements for the drug; and (3) the sponsor has failed to present to FDA a program for assuring that such information will be publicized promptly and adequately to the medical profession in subsequent advertisements, or if such a program has been presented to FDA but is not being followed by the sponsor. Under § 202.1(j)(1)(iii), a sponsor must provide to FDA a program for assuring that significant new adverse information about the drug that becomes known (i.e., use of drug may cause fatalities or serious damage) will be publicized promptly and

adequately to the medical profession in any subsequent advertisements. Under § 202.1(j)(4), a sponsor may voluntarily submit advertisements to FDA for comment prior to publication.

Disclosures to the Public

Under § 202.1, advertisements for human and animal prescription drug and biological products must comply with the standards described in that section.

Under § 202.1(j)(1), if information that the use of a prescription drug may cause fatalities or serious damage has not been widely publicized in the medical literature, a sponsor must include such information in the advertisements for that drug.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	No. of	No. of	Total	Average	Total
	Respondents	Responses per	Annual	Burden per	Hours
		Respondent	Responses	Response	
202.1(e)(6)Waiver request to FDA	1	1	1	12	12
202.1(j)(1)Submission of	1	1	1	2	2
advertisement to FDA for prior					
approval					
202.1(j)(1)(iii)Providing a program	1	1	1	12	12
to FDA for assuring that adverse					
information about the drug will be					
publicized					
202.1(j)(4)Voluntarily submitting the	113	6	678	20	13,560
advertisement to FDA prior to					
publication for comment					
Total					

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Third-Party Disclosure Burden¹

Table 2Estimated Alindar Time-1 arty Disclosure Burden								
21 CFR Section	No. of	No. of	Total	Average	Total Hours			
	Respondents	Disclosures per	Annual	Burden per				
		Respondent	Disclosures	Disclosure				
202.1Advertisements prepared in accordance with § 202.1	541	46.5	25,157	400	10,062,800			
202.1(j)(1)Including information about the drug's fatalities or serious damage in the advertisement	1	1	1	40	40			
Total			·	·	10,062,840			

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-04262 Filed 02/26/2014 at 8:45 am; Publication Date: 02/27/2014]